

SpeedySwab™

Rapid COVID-19 + FLU A&B Antigen Self-Test

QUICK REFERENCE INSTRUCTIONS

Carefully read the instructions below before performing the test. Failure to follow the instructions may result in inaccurate test results.

STORAGE AND STABILITY

Store kit between 36-86°F (2-30°C). Ensure all test components are at room temperature before use.

BEFORE GETTING STARTED

1.

Check expiration date on the outside of the box, Do not use beyond the expiration date. For the most current expiration dates of this test, please refer to: <https://www.fda.gov/covid-tests>.

2.

Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples.

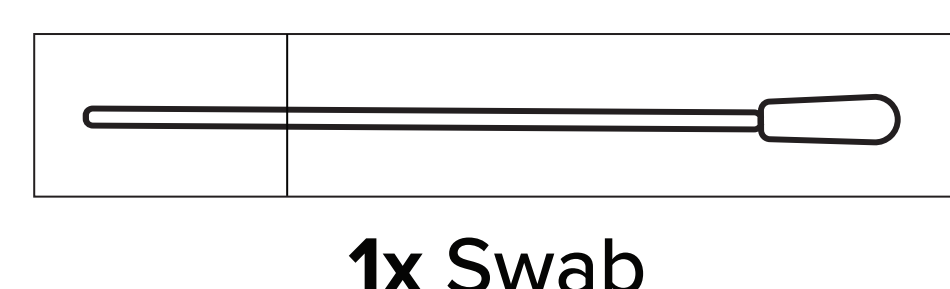
NOTE: It is recommended that gloves be worn during testing. A face mask should be worn if swabbing others.

3.

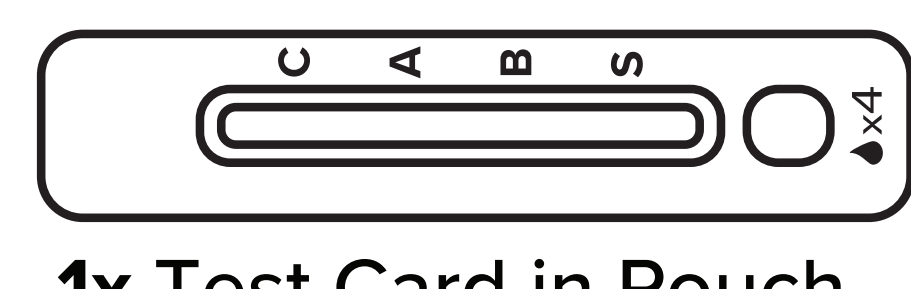
Clean the tabletop on which the test will be performed. Before testing, read the User Instructions carefully. The test kit and specimen must be at room temperature (60-86°F) for testing.

PREPARE THE MATERIALS

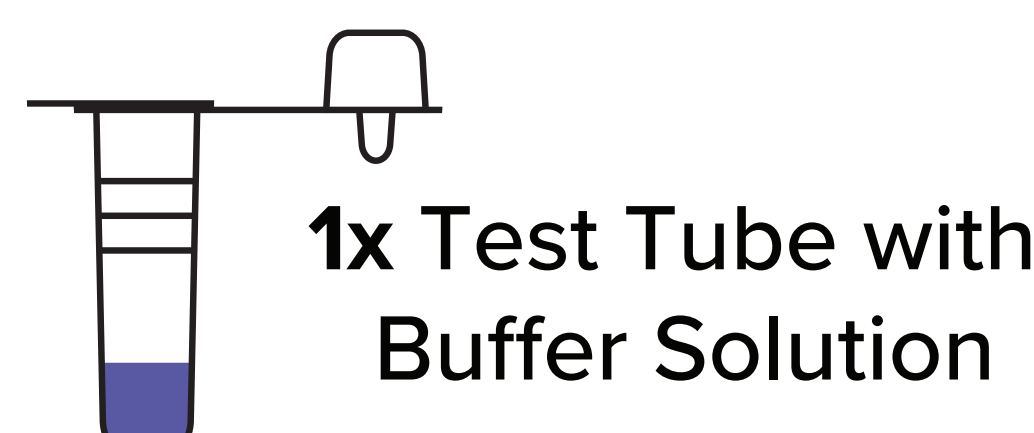
MATERIALS PROVIDED:



1x Swab



1x Test Card in Pouch



1x Test Tube with Buffer Solution

Materials required but not provided: A clock or timer;
Recommended materials: Disposable gloves and mask, if swabbing others

4.

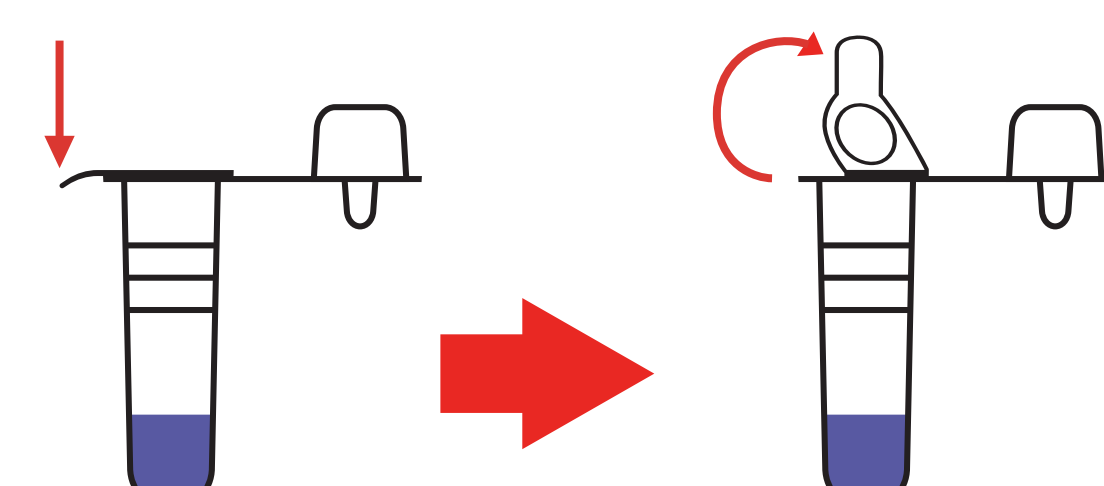
Arrange the materials on a clean, dry, flat surface.

Your box may contain more than one test kit. Use only one of each of the materials provided for each test

DO NOT open the individual pouches until instructed to do so.

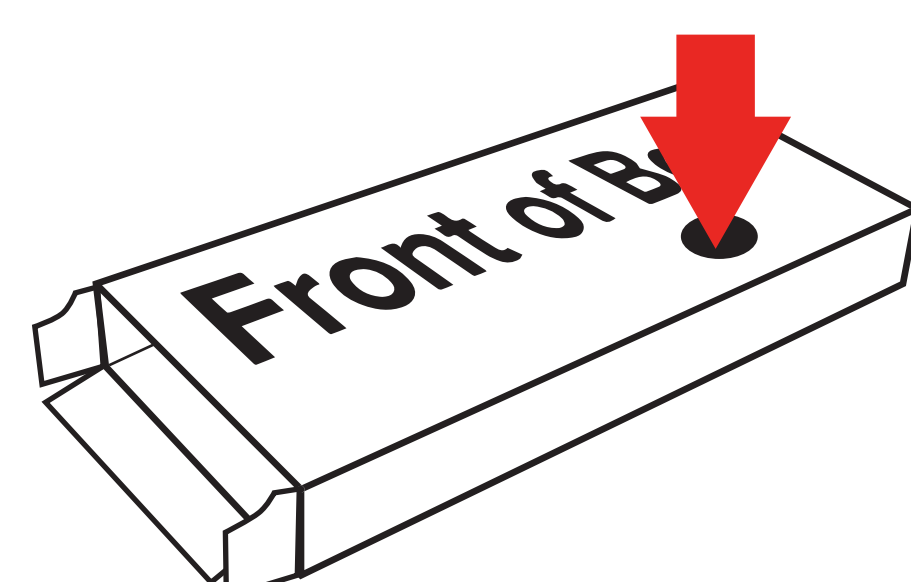
5.

Pick up the Test Tube and remove the sealing foil of the tube.



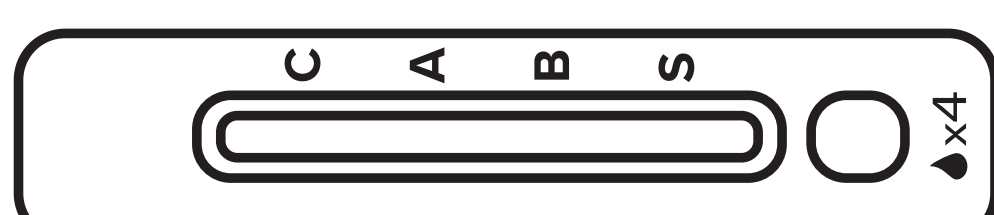
6.

Place the buffer solution tube in the front of box labeled "Push Tube Here."



7.

Remove the Test Card from its foil pouch.



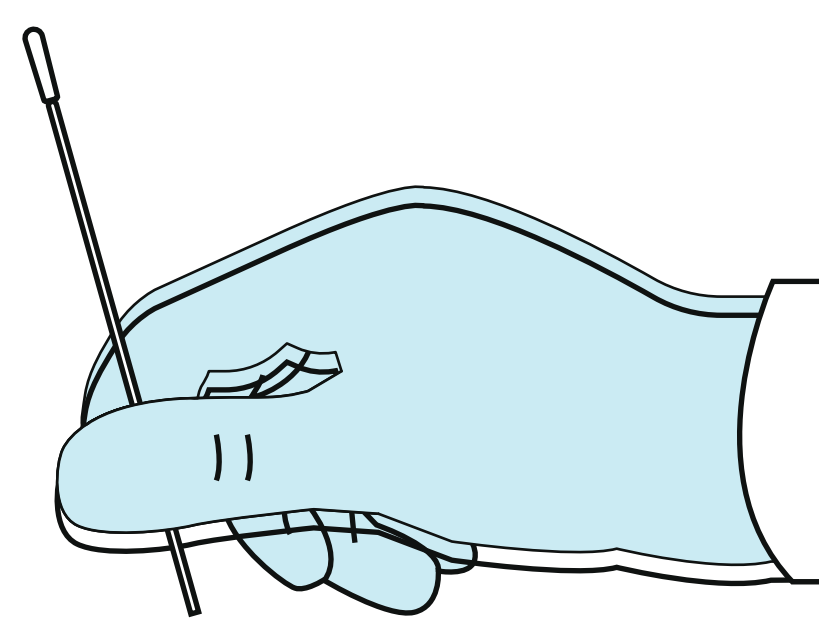
NOTE: Use the Test Card within one hour of opening the test pouch.

PERFORMING THE TEST

8.

Open swab package from its stick end and remove the swab from this end.

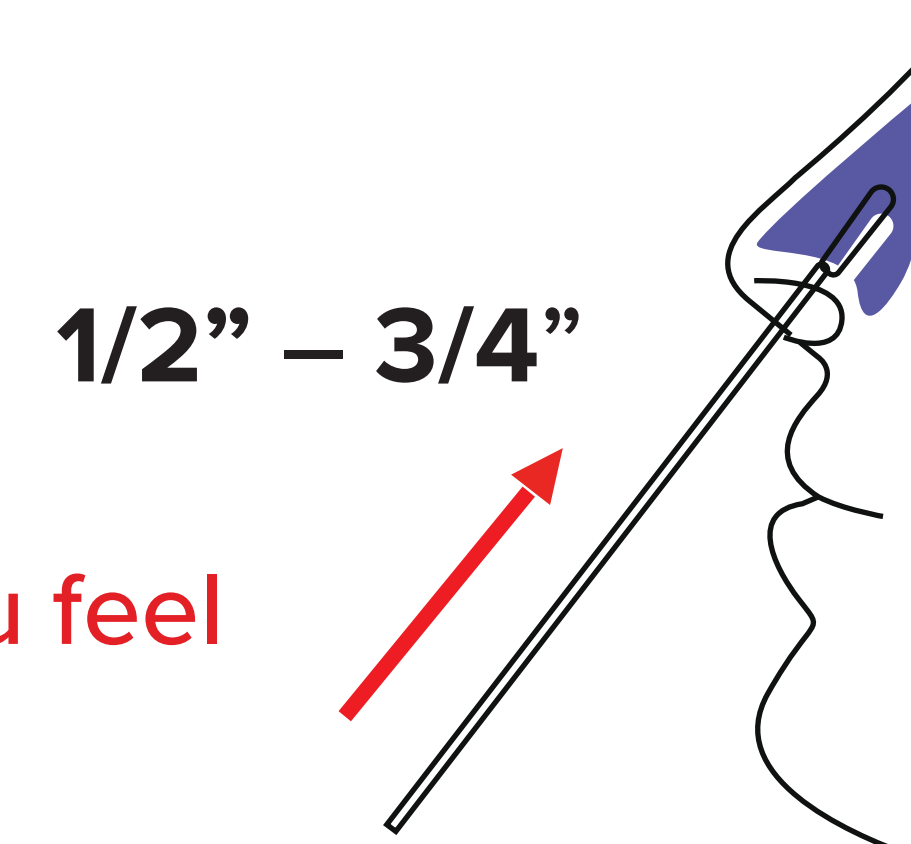
DO NOT touch the swab head.



9.

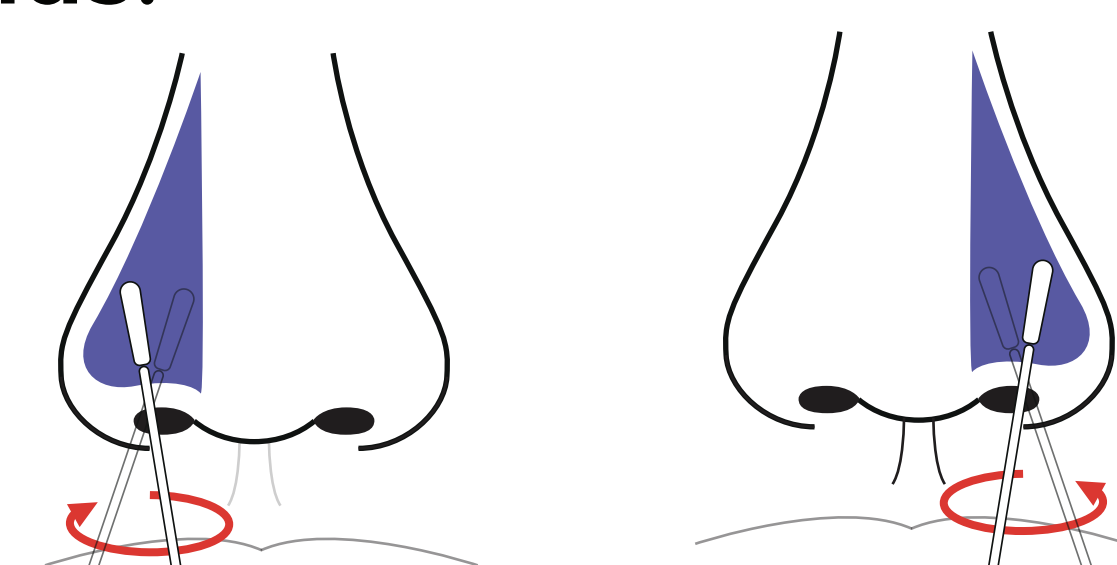
Gently insert the swab 1/2 to 3/4 inch into a nostril.

DO NOT insert the swab any farther if you feel any resistance.



Using medium pressure, rub and rotate the swab against the inside walls of the nostril, making at least 5 circles for at least 15 seconds.

REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB.



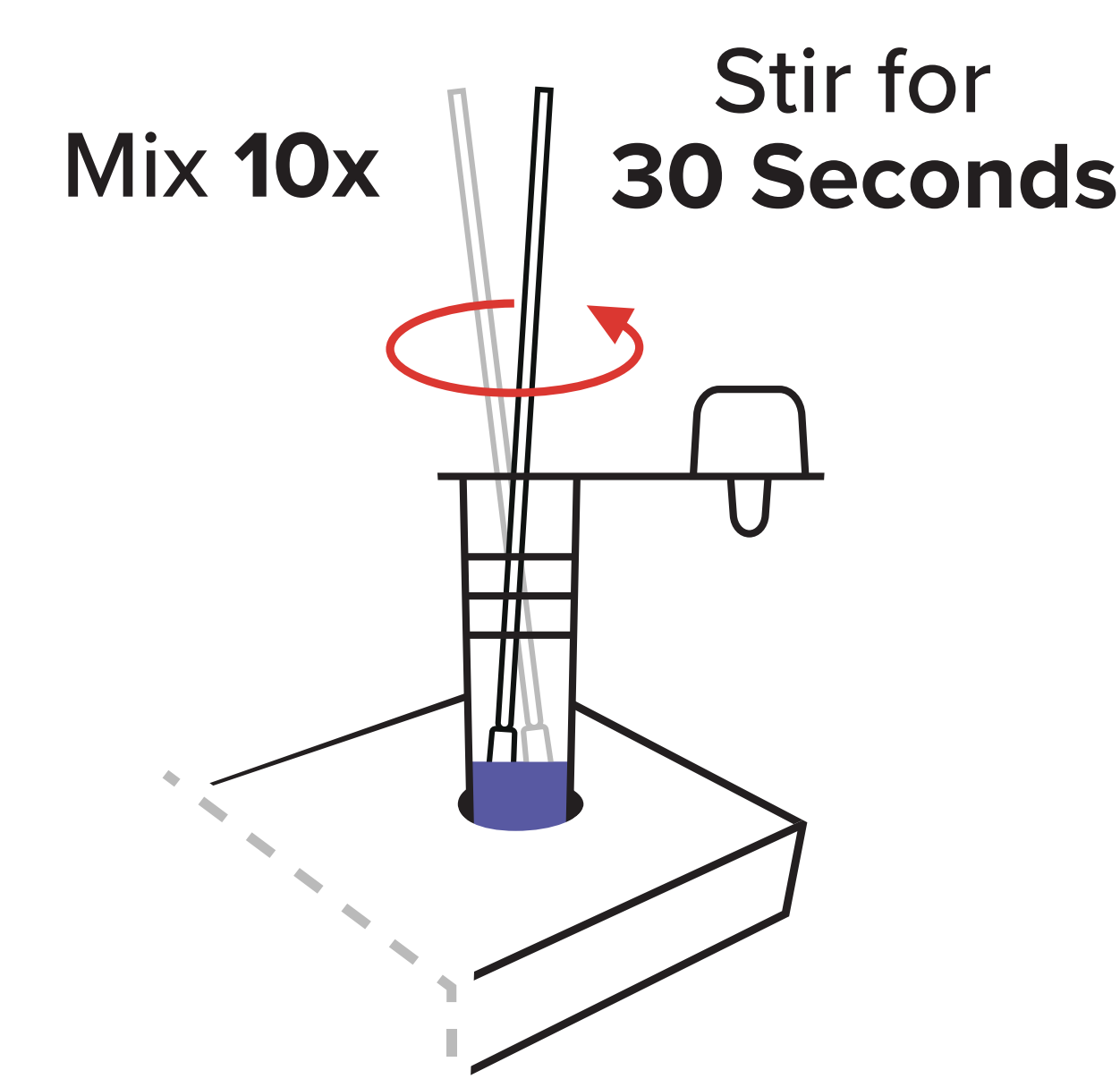
5x for 15 seconds, each nostril

NOTE: If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

STOP: Did you swab BOTH nostrils? Inaccurate test results may occur if the nasal sample is not properly collected.

10.

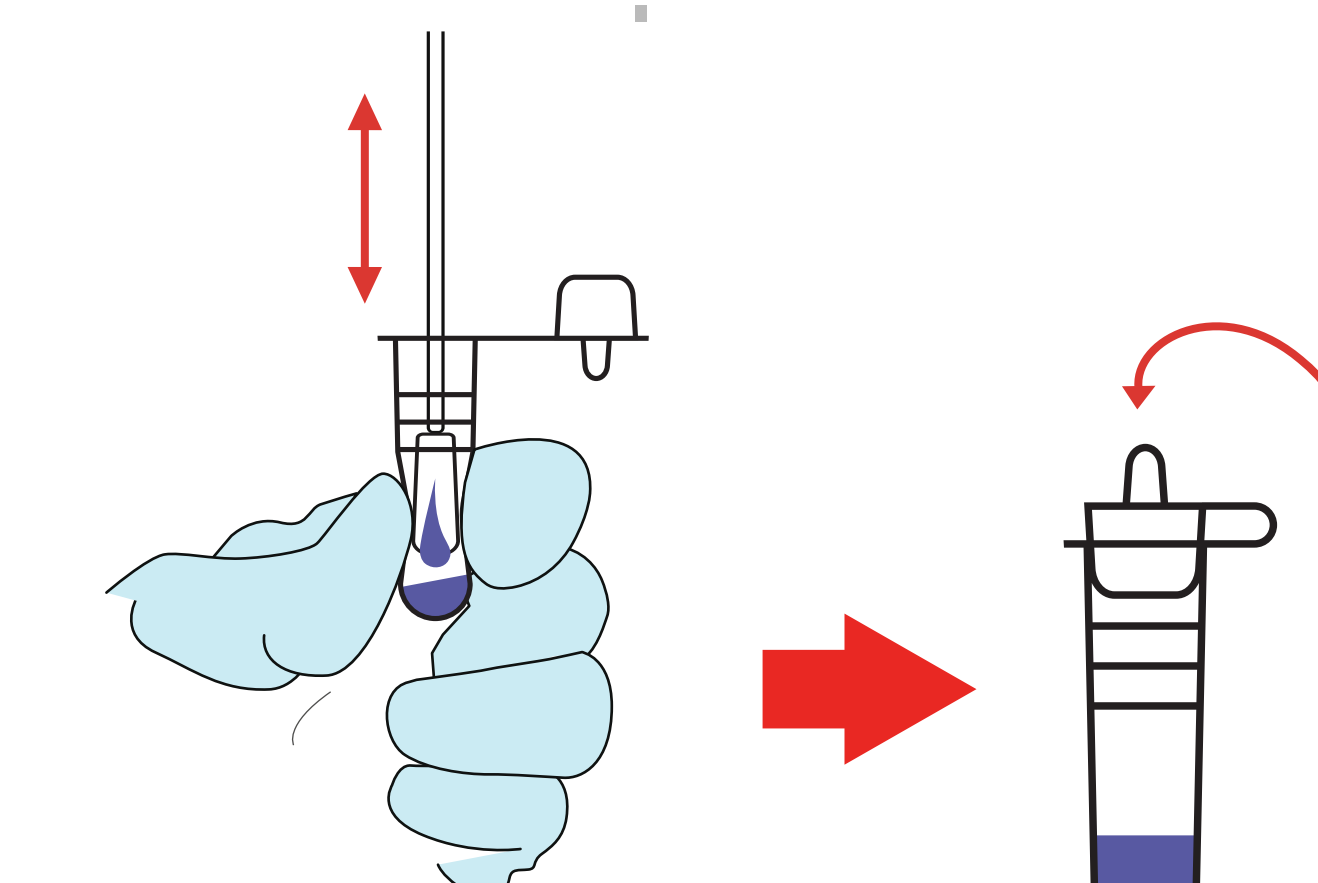
Place the swab into the buffer solution and completely immerse the swab head in the sample.



Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least 10 times for 30 seconds, keeping the swab tip submerged in the buffer solution the entire time.

11.

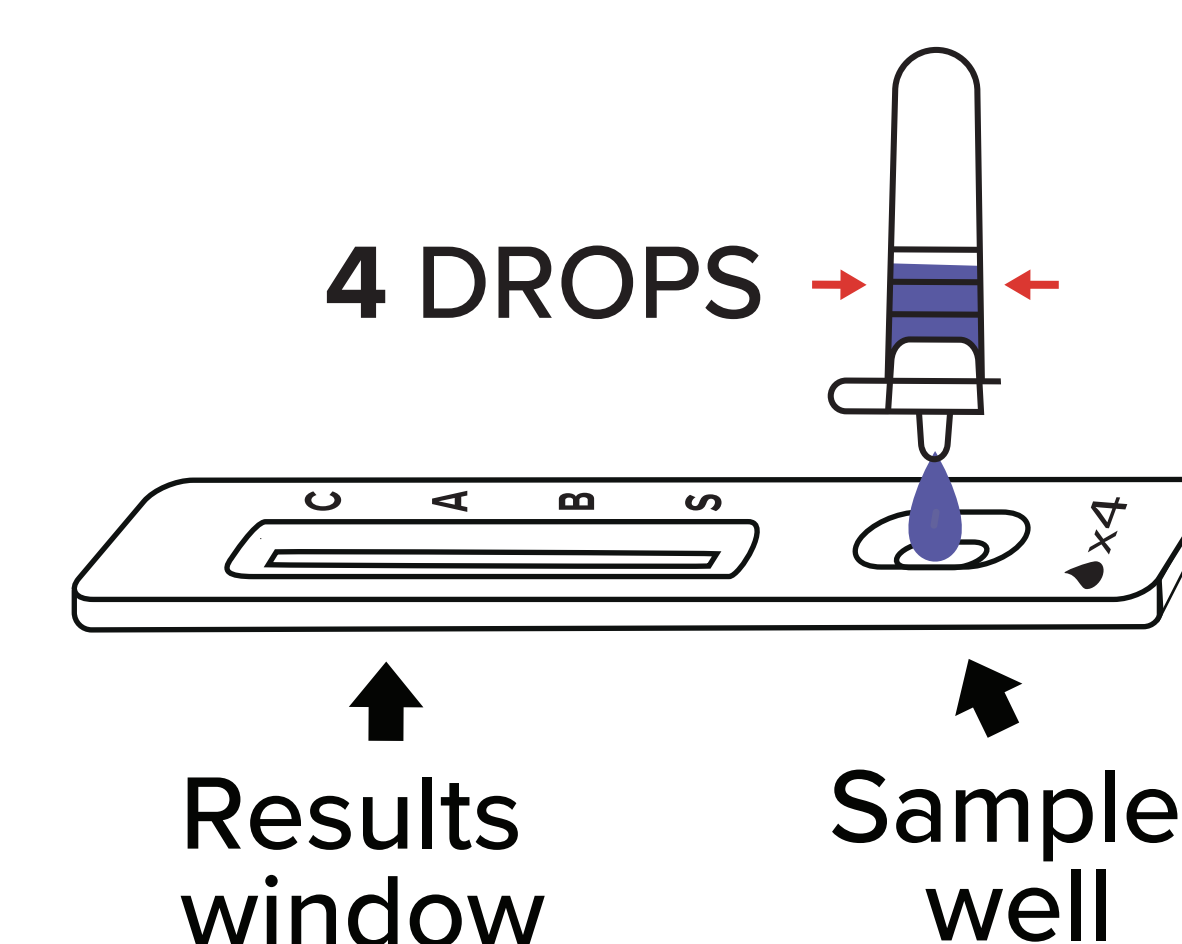
Squeeze the tube 5 times with your fingers to ensure that the sample on the swab is fully mixed into the buffer solution.



Attached the dropper cap to the test tube.

12.

Squeeze only 4 DROPS of the Buffer Solution into the sample well.



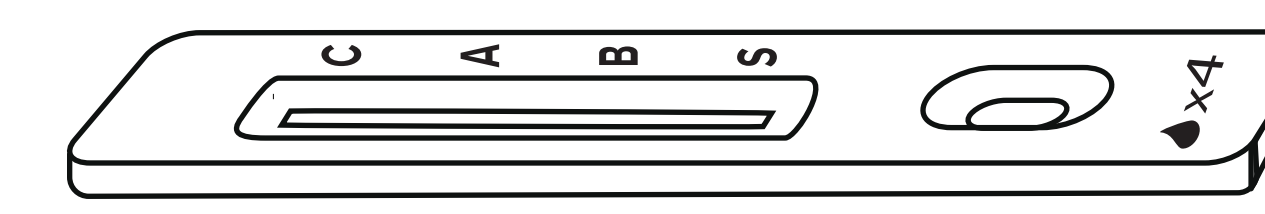
DO NOT squeeze more than 4 drops from the tube. Additional sample volume may yield inaccurate results.

13.

Set a timer and read the test result at 15 minutes.



DO NOT disturb the card during this time. Inaccurate results can occur if the card is disturbed.

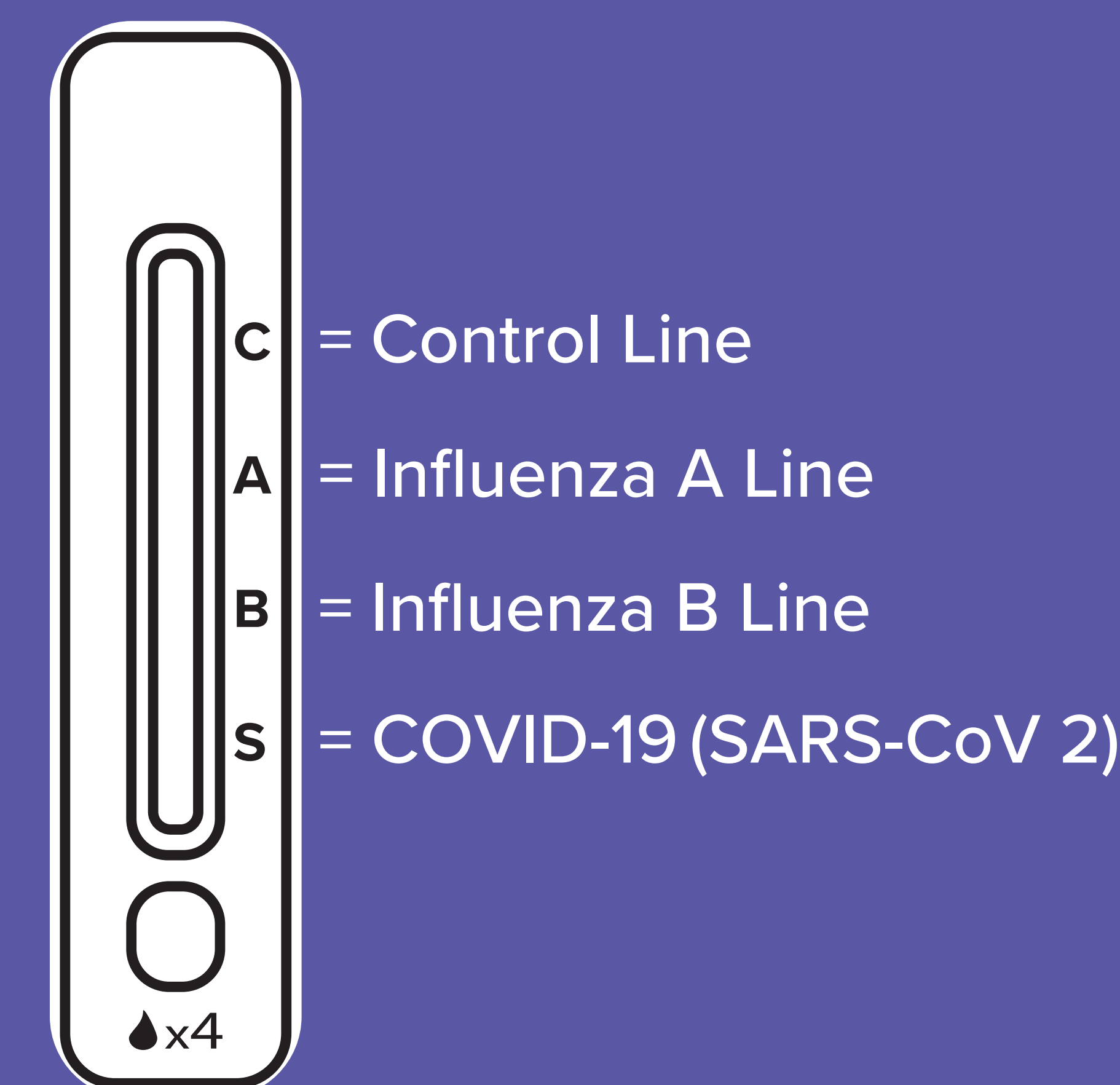


DO NOT interpret test result before 15 minutes after 20 minutes.

TEST RESULT INTERPRETATION

Test results are read and interpreted visually. Read result at 15 minutes with good lighting.

WARNING: Do not read the result before 15 minutes or after 20 minutes. Inaccurate test interpretations may occur.



Look for lines next to 'C' (Control), 'A', 'B' and 'S'.

FOR EASE OF USE, HOLD TEST CARD NEXT TO THE IMAGES BELOW AND AT RIGHT

INVALID RESULTS

If a control line is not visible at "C" after 15 minutes, even if any other line is visible in the results window, **THE TEST HAS FAILED** and is considered **invalid**.

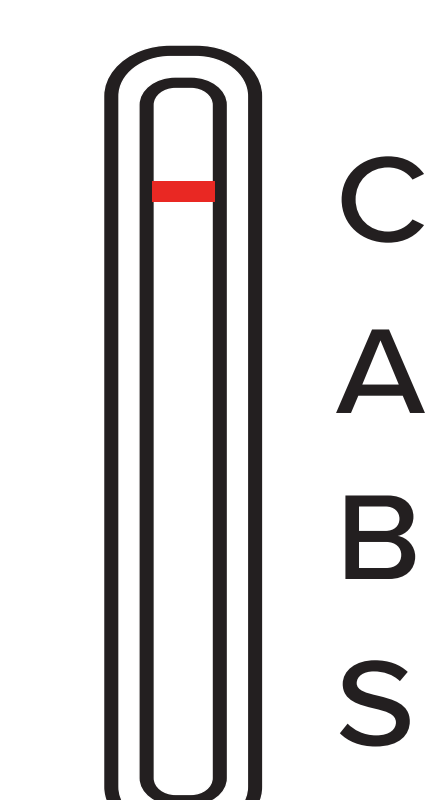


STOP: If the test is invalid, repeat the test procedure using a new test kit and sample.

NEGATIVE RESULTS

If the control line at "C" is visible and you do not see a line at 'A', 'B' or 'S', it means you may not have COVID-19, Flu A or Flu B virus.

If you still have COVID-19, Flu A, or Flu B symptoms, you should seek follow up care with your healthcare provider.



POSITIVE RESULTS

If the control line at "C" is visible and any other line or multiple lines on 'A', 'B' and/or 'S' appear, the test is **positive**.

NOTE: Any red line, no matter how faint, should be considered an Indication of a positive result.



COVID-19 Positive



Flu A Positive



Flu B Positive



Flu A+ COVID-19 Positive



Flu B+ COVID-19 Positive



Flu A+ Flu B Positive



Flu A+B+ COVID-19 Positive

Consult your healthcare provider to discuss your positive test result. Self-isolate at home per CDC recommendations to stop spreading virus to others.

UNDERSTANDING YOUR RESULTS

INVALID RESULT:

This test did not work. The result should not be used. The test cannot determine if you have COVID-19, influenza A (Flu A), or influenza B (Flu B). The test needs to be repeated with a new kit and sample.

NEGATIVE RESULT:

The virus from COVID-19, Flu A, and/or Flu B were not detected in the sample. A negative result does not mean that you do not have COVID-19, Flu A and/or Flu B infection. There is a higher chance of false negative results with antigen tests compared to laboratory-based molecular tests. If you tested negative and continue to experience COVID-19, Flu A and/or Flu B-like symptoms, you should seek follow-up care with your healthcare provider.

POSITIVE RESULT:

The COVID-19, Flu A and/or Flu B virus(es) were detected in your sample. It is very likely that you have the respective infection(s) and are contagious. Please contact your healthcare provider or your local health authorities and follow local guidelines for self-isolation. There is a small chance that this test can give you a positive result that is incorrect (a false positive). Report your test result(s) at MakeMyTestCount.Org – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

AFTER TEST IS COMPLETED, DISPOSE OF USED MATERIALS IN HOUSEHOLD TRASH.



SpeedySwab™

Rapid COVID-19 + FLU A&B Antigen Self-Test

The ongoing COVID-19 pandemic, along with other seasonally prevalent illnesses such as influenza (Flu), continue to be among the world’s most pressing healthcare issues. While contagious respiratory illnesses such as COVID-19 and influenza share similar symptoms and means of transmission, they are caused by different viruses. The Centers for Disease Control and Prevention (CDC) has also raised concerns about the potential co-infection with two or more of the respiratory viruses. There is an urgent need for rapid COVID-19 and Influenza A/B diagnostic over-the-counter tests so that patients can seek appropriate treatment with their healthcare provider before their symptoms worsen. These rapid COVID-19 and Influenza A/B diagnostic over-the-counter tests are intended for non-prescription self-use and/or as applicable by an adult lay user testing another person 2 years or older in a non-laboratory setting. Shenzhen WatMind, legal manufacturer for WatMind USA, has developed an over-the-counter at home test for the differential detection of the SARS-CoV-2, Influenza A and Influenza B antigens using anterior nares nasal swabs specimens. The test detects SARS-CoV-2 nucleocapsid protein, and Influenza A and B proteins. The investigational test may also be used as a point-of-care diagnostic test at sites operating under a CLIA Certificate of Waiver. The SpeedySwab Rapid COVID-19 + Flu A&B Antigen Self-Test is FOR INVESTIGATIONAL USE ONLY - The performance characteristics of this product have not been established.

INTENDED USE

The SpeedySwab Rapid COVID-19 + Flu A&B Antigen Self-Test is a lateral flow immunoassay intended for the qualitative and differential detection of nucleocapsid protein from SARS-CoV-2, influenza A and influenza B proteins using self-collected anterior nares nasal swab samples from individuals aged 14 years or older.

This test is authorized for non-prescription home use with self-collected anterior nares nasal swab samples from individuals aged 14 years or older with symptoms of SARS-CoV-2, influenza A and influenza B within the first 6 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected anterior nasal swab samples from individuals aged 2 years or older with symptoms of SARS-CoV-2, influenza A and influenza B within the first 6 days of symptom onset.

Results are for the simultaneous identification of SARS-CoV-2 nucleocapsid protein, influenza A and influenza B proteins. Antigen is generally detectable from specimens collected using nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Individuals who test positive with the SpeedySwab Rapid COVID-19 + Flu A&B Antigen Self-Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary. Negative results should be treated as presumptive, do not rule out SARS-CoV-2, influenza A and influenza B infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual’s recent exposures, history and the presence of clinical signs and symptoms consistent with SARS-CoV-2, influenza A and influenza B, and confirmed with a molecular assay, if necessary. Individuals who test negative and continue to experience SARS-CoV-2 and/or influenza like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 and/or influenza infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All healthcare providers will report all test

results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The SpeedySwab Rapid COVID-19 + Flu A&B Antigen Self-Test is authorized for non-prescription self-use and/or as applicable an adult lay user testing another person 2 years or older in a non-laboratory setting. The SpeedySwab Rapid COVID-19 + Flu A&B Antigen Self-Test may also be authorized under the EUA use by untrained healthcare professionals operating under CLIA-Waiver license.

HOW TO USE THIS TEST

PLEASE FOLLOW THE INSTRUCTIONS IN THIS QUICK REFERENCE GUIDE INCLUDING PAYING CLOSE ATTENTION TO THE TEST RESULTS INTERPRETATION SECTION. FOR EASE OF INTERPRETATION TESTS CAN BE HELD NEXT TO EACH RESULT.

Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and influenza, and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19 and influenza, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.

If you test negative but continue to have symptoms of COVID-19 and influenza, and both test(s) are negative, you may not have COVID-19 or influenza, however you should follow-up with your healthcare provider.

If your test is positive, then proteins from the virus that causes COVID-19 and/or influenza have been found in your sample and you likely have COVID-19 and/or influenza.

WARNINGS, PRECAUTIONS AND SAFETY INFORMATION

• Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

• Serial testing may be performed in individuals with negative results at least twice over three days (with 48 hours between tests) or symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial testing.

• Test components are single-use. Do not re-use.

• Do not use kit past its expiration date.

• Do not touch the swab tip.

• Once opened, the test card should be used within 60 minutes.

• Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.

• Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table in the next column). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice: <https://www.poisson-help.org> or 1-800- 222-1222.

Chemical Name	GHS Code for each Ingredient	Concentrations
Proclin 300	H317, allergic skin reaction	0.1%
Trimethylsilyl acetamide	H316, mild skin irritation	0.03%

• For more information on EUAs please visit: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

• For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

FREQUENTLY ASKED QUESTIONS

Q: WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

A: Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect test result (see Warnings and Result Interpretation sections for more information).

Potential benefits include:

- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.

- The results of this test may help limit the potential spread of COVID-19 and influenza to your family and others in your community. For more information on EUAs go here: <https://www.fda.gov/emergen-cypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization>

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

A: There are different kinds of tests for the COVID-19 and influenza. Molecular tests detect genetic material from the virus. Antigen tests, such as the SpeedySwab Rapid COVID-19 + Flu A&B Antigen Self-Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 and influenza than a molecular test would.

Q: HOW ACCURATE IS THIS TEST?

A: Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 and influenza when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at www.SpeedySwab.com.

Q: WHAT IF I HAVE A POSITIVE TEST RESULT?

A: A positive result means that it is very likely you have COVID-19 or influenza because proteins from the virus that causes COVID-19 or influenza were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

Q: WHAT IF I HAVE A NEGATIVE TEST RESULT?

A: A negative test result indicates that antigens from the virus that cause COVID-19 and influenza were not detected in your sample. However, if you have symptoms of COVID-19 or influenza, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out COVID-19 and influenza; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?
A: An invalid result means the test was not able to tell if you have COVID-19 and influenza or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

LIMITATIONS

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 and influenza as compared to a molecular test, especially in samples with low viral load.

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between XXX to XXX, 2023. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of COVID-19 and influenza and their prevalence, which change over time.

FREQUENTLY ASKED QUESTIONS

- If the test is positive, then proteins from the virus that causes COVID-19 and influenza have been found in the sample and you likely have COVID-19 and/or influenza.

- All COVID-19 and influenza antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19 and influenza, and both test(s) are negative, you may not have COVID-19 and influenza, however you should follow-up with a healthcare provider.

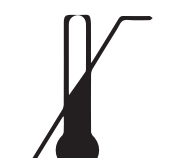
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.

- Incorrect test results may occur if a specimen is incorrectly collected or handled.

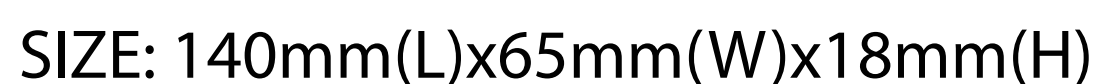
FREQUENTLY ASKED QUESTIONS

This test is intended to be used as an aid in the clinical diagnosis of infection with the virus that causes COVID-19 and influenza. Do not use this test as the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are concerned at any time. Individuals should provide all results obtained with this product to their healthcare provider for public health reporting.

INDEX OF SYMBOLS

	Manufacturer		Date of manufacture
	Contains sufficient for <n> tests		Catalogue number
	Temperature limit		Use-by date
	Do not reuse		Batch code

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SIZE: 140mm(L)x70mm(W)x23mm(H)



SIZE: 150mm(L)x75mm(W)x40mm(H)